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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,392	08/21/2002	Kotoku Kurachi	UM-06855	7886

7590

06/16/2005

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,392

Applicant(s)

KURACHI ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-20 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, drawn to a recombinant expression vector comprising one or more age regulatory sequence selected from SEQ ID NO:1 or a portion of SEQ ID NO:1 and a method of using the same recombinant expression vector.

Group II, claims 1-2, drawn to selected from SEQ ID NO:3 or a portion of SEQ ID NO:3 and a method of using the same recombinant expression vector.

Group III, claims 3-18, drawn to a substantially purified nucleic acid sequence comprising at least a portion of SEQ ID NO:93, a recombinant expression vector comprising an age-related regulatory sequence selected from SEQ ID NO:93 and portions thereof, a host cell containing the same recombinant expression vector and a method for expressing a nucleic acid sequence of interest using the same recombinant expression vector. It appears that claims 4-5 should be dependent on claim 3 rather than claim 1 because the recited SEQ ID Nos in claim 5 are portions of SEQ ID NO:93.

Group IV, claims 19-20, drawn to a substantially purified nucleic acid sequence comprising a nucleotide sequence selected from at least a portion of SEQ ID NO:85 and at least at least a portion of SEQ ID NO:92, and a method for expressing a nucleic acid sequence of interest using a nucleotide sequence selected from SEQ ID NO:92, a portion of SEQ ID NO:92, SEQ ID NO:85, a portion of SEQ ID NO:85, SEQ ID NO:89 and SEQ ID NO:90.

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The technical feature linking Groups I to IV appears to be a nucleic acid sequence that has age-related regulatory activity. However, SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:93 (derived from the hFIX gene), SEQ ID NOs: 85 and 92 (both are derived from the hPC gene) and their portions have no substantial common core structures one from the others. Since these nucleic acid sequences and their portions have different nucleotide sequences one from the others, and each nucleotide sequence becomes a basis for the "special technical feature" for that Group and not required for the other Groups, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction:

A. Should Applicants elect the invention of Group III, claims 3-5, 7-10, 12-18 are generic to a plurality of disclosed patentably distinct species of a portion of SEQ ID NO:93 comprising:

A single specifically named SEQ ID NO listed in the Markush group of either claim 5 or claim 10.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 7-17 are generic to a plurality of disclosed patentably distinct species of an encoded protein comprising:

A single specifically named encoded protein as listed in the Markush group of claim 8.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 7-17 are generic to a plurality of disclosed patentably distinct species of promoter sequence comprising:

A single specifically named promoter sequence as listed in the Markush group of claim 9.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 13 and 16 are generic to a plurality of disclosed patentably distinct species of a host cell comprising:

A single specifically named host cell as listed in the Markush group of claim 16.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

B. Should Applicants elect the invention of Group IV, claims 19-20 are generic to a plurality of disclosed patentably distinct species of a nucleotide sequence comprising:

A single specifically named nucleotide sequence as listed in the Markush group of claim 20.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


QUANG NGUYEN, PH.D.
PATENT EXAMINER